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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 41

Application Number: 08/485129

Filing Date: 6/7/95

Appellant(s): Wallach et al.

Roger L. Browdy
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 9/25/2001.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

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A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is partially correct. The rejection of claim 63 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (There is no support in the specification as originally filed for the claimed DNA molecules. The oligonucleotides disclosed in pages 9-11 of the specification are complementary to the DNA encoding TBP-II. Therefore, they do not encode TBP-II, because they are antisense to the TBP-II molecule. The instant claim recites oligonucleotides that encode DNA encoding TBP-II. There is no disclosure of such an invention in the specification

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as originally filed.) as enunciated in paragraph 6 of the Office Action mailed 1/30/2001 is withdrawn in view of appellants arguments in the instant Brief.

(7) *Grouping of Claims*

Appellant's brief includes a statement that the claims stand or fall together.

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

A) Claims 11-13,35-38,43,44,46-49,51-54,56-61,63,64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to

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the artisan that the applicant had possession at the time of invention of the claimed DNAs and molecules containing said DNAs.

The instant claims encompass an isolated DNA molecule or vectors or host cells which contain said DNA wherein said DNA encodes a protein consisting of naturally occurring TBP-II. There is no disclosure in the specification of an intact DNA sequence which encodes said molecule. There is no disclosure in the specification of any DNA sequence which encodes the claimed DNA. The claimed molecule recites physical features of a TBP-II protein and the amino acid sequences of a 10-13 amino acid sequence of the N terminal of a molecule that contains at least 250 amino acids. There is no disclosure in the specification of any DNA sequence which encodes the claimed molecule. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has not provided even a

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single DNA sequence which encodes the claimed DNA . The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991).

Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

B) Claims 35-38,43,44,46-49,51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed DNA molecules encoding the fragment of claim 35, part (2) or claim 36, part (2) or claim 46, part (2) or claim 51, part (2). Regarding original claim 11, said claim is drawn to a DNA molecule encoding TBP II, not a fragment thereof. There is no disclosure in the specification as originally filed of DNA molecules encoding the aforementioned fragments recited in the claims. There is no written description of the scope of the claimed inventions in the specification as originally filed (the claimed inventions constitute new matter).

The rejection of claim 63 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (There is no support in the specification as originally filed for the claimed DNA molecules. The oligonucleotides disclosed in pages 9-11 of the specification are complementary to the DNA encoding TBP-II. Therefore, they do not encode TBP-II, because they are antisense to the TBP-II molecule. The instant claim recites oligonucleotides that encode DNA encoding TBP-II. There is no disclosure of such an invention in the specification as originally filed.) as enunciated in paragraph 6 of the Office Action mailed 1/30/2001 is withdrawn in view of appellants arguments in the instant Brief.

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(II) Response to Argument

A) Claims 11-13,35-38,43,44,46-49,51-54,56-61,63,64 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Appellants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed DNAs and molecules containing said DNAs.

Appellants arguments are based on the syllogism enunciated in page 18 of said Brief. In said syllogism, appellant appears to argue that the nucleic acid sequence encoding the entire TBP II protein is an inherent property of the TBP II protein visa vie the inherent amino acid sequence of TBP II. The specification discloses physical features of a TBP-II protein and the amino acid sequences of a 10-13 amino acid sequence of the N terminal of a molecule that contains at least 250 amino acids. There is no disclosure in the specification of an isolated

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nucleic acid encoding TBP-II. Thus, there is no disclosure in the specification of the identity of approximately 750 nucleic acids which encode TBP-II. In addition, the DNA sequence is not an inherent property of the TBP II protein because proteins do not contain nucleic acids.

Regarding point 3 of said syllogism, while the amino acid sequence of TBP II is an inherent property of said protein, the nucleic acid sequence encoding said molecule is not an inherent property of the protein. Proteins are made of amino acids. Nucleic acids are made of nucleotides. An isolated protein in itself reveals nothing about the nucleic acid which encodes it. Figure 2 in the specification depicts the purified TBP II protein disclosed in the specification. Said isolated protein reveals no information about the nucleic acid sequence encoding said protein. While the amino acid sequence of said protein is an inherent property of said protein, the nucleic acid encoding said amino acid sequence cannot be an inherent property of said protein because proteins and nucleic acids are chemically different molecules (e.g. amino acids versus nucleotides). For example, the isolated protein depicted in Figure 2 of the specification reveals nothing about the nucleic acid sequence encoding said protein. The MPEP section 2163.07(a) states:

2163.07(a) Inherent Function, Theory, or Advantage

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing

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explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. In re Reynolds, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); In re Smythe, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

As per Figure 2 of the specification, the nucleic acid sequence is not present in the isolated TBP-II protein and is therefore not an inherent property of said protein. While the nucleic acid encoding a protein can be deduced based on the amino acid sequence of a protein, it is not an inherent property of the protein. In the absence of the disclosure of the entire amino acid sequence encoding the protein, there is no disclosure in the specification of any nucleic acid encoding a TBP II protein. There is no disclosure in the specification of the nucleic acid sequence of a DNA molecule encoding TBP II. The amino acid sequence of TBP II is not disclosed in the specification. While the amino acid sequence of TBP II is an inherent property, **in order to determine the nucleic acid sequence based on said sequence, disclosure of said sequence is required as is the actual conversion of the amino acid sequence data into**

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appropriate nucleotides (e.g. codons) encoding said protein. The amino acid sequence of TBP II was not known by applicant at the time of filing of the instant application, therefore, applicant was not in possession of the claimed nucleic acids. **In addition, the step of converting the amino acid data into nucleotides encoding said molecule was not performed and therefore appellant was not in possession of the claimed nucleic acids.** There is no disclosure in the specification of an actual nucleic acid sequence of a DNA encoding TBP II. For the reasons mentioned above, it is clear that a DNA sequence encoding a protein is not an inherent property of a protein.

Furthermore, according to point 3 of appellants syllogism, a disclosure of an isolated protein (with an appropriate publication date) would constitute prior art under 35 U.S.C. 102 with regards to a claim reading on a nucleic acid encoding said protein. This is clearly repugnant to currently accepted biotechnology patent practice.

Appellants syllogism puts forth an argument as to why the DNA sequence encoding TBP II would be obvious based on the inherent amino acid of TBP II. In view of the fact that there is no literal description of a nucleic acid sequence encoding a DNA sequence in the specification, applicants syllogism would at best attempt to explain why the claimed nucleic acid is obvious in view of the inherent amino acid sequence of the TBP II protein. For the reasons disclosed above, the nucleic acid encoding a protein is not an inherent property of the protein. In order to render obvious the nucleic acid sequence of a protein based on the protein sequence **disclosure of said sequence is required as is the conversion of the amino acid**

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sequence into appropriate nucleic acids encoding said protein. This information is not disclosed in the instant application. In addition, obviousness is not the appropriate standard with regards to issues of written description. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application

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need not describe the claimed subject matter in exactly the same terms as used in the claims... . ."), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

There is no disclosure in the specification of an isolated nucleic acid encoding TBP II or the nucleic acid sequence encoding said molecule. The nucleic acid sequence is not an inherent property of a protein. While the amino acid sequence of TBP II is an inherent property, **in order to determine the nucleic acid sequence based on said sequence, disclosure of said sequence is required as is the actual conversion of the amino acid sequence data into appropriate nucleic acids encoding said protein.** The amino acid sequence of TBP II was not known by applicant at the time of filing of the instant application, therefore, applicant was not in possession of the claimed nucleic acids. **In addition, the step of converting the amino acid data into nucleic acids encoding said molecule was not performed and therefore appellant was not in possession of the claimed nucleic acids.** Therefore, at the time of filing appellant was not in possession of the claimed invention. Regarding claims 35-38,43,44,46-49,51-54,56-61,63,64 there is no disclosure in the specification of nucleic acids encoding the fragments of TBP II recited in the claims. Appellants syllogism does not disclose the identity of said fragments or even render the identity of said fragments obvious. Regarding appellants comments , the specification discloses physical features of a TBP-II protein and the

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amino acid sequences of a 10-13 amino acid sequence of the N terminal of a molecule that contains at least 250 amino acids. The claimed fragments and probes encompass nucleic acids derived from the approximately 720 nucleic acids encoding TBP-II that are not disclosed in the specification. In addition, regarding the fragment of claim 35 section(2) (and other such fragments recited in the claims), there is no disclosure in the specification of nucleic acid fragments encoding TBP-II fragments with the particular functional activity recited in the claim.

B) Claims 35-38,43,44,46-49,51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the claimed DNA molecules encoding the fragment of claim 35, part (2) or claim 36, part (2) or claim 46, part (2) or claim 51, part (2). Regarding original claim 11, said claim is drawn to a DNA molecule encoding TBP II, not a fragment thereof. There is no disclosure in the specification as originally filed of DNA molecules encoding the aforementioned fragments recited in the claims. There is no written description of the scope of the claimed inventions in the specification as originally filed (the claimed inventions constitute new matter).

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Regarding appellants comments, the specification page 15, lines 11-17 refers to protein molecules, not nucleic acid molecules. Regarding the specification, page 4, said passage refers to nucleic acids encoding **proteins**, not fragments of a protein with a particular functional activity. Regarding the specification, page 7, said passage of the specification refers to **proteins** (e.g. intact proteins) and also does not specify that “proteins substantially homologous” refers to protein fragments with a particular functional. In fact, “proteins substantially homologous” refers to **proteins** (e.g. intact proteins), not fragments of proteins. The passage of the specification to which appellant refers actually defines “polypeptide” as encompassing TBP-II molecules shorter than intact TBP-II. There is no disclosure in the specification that “proteins substantially homologous” refers to polypeptides smaller than intact TBP-II. In fact, the specification clearly differentiates between protein (intact molecule) and polypeptide (shorter than intact molecule) in the passage of page 7 of the specification which appellant quotes. There is no disclosure in the specification as originally filed of nucleic acids encoding TBP-II polypeptides with the functional properties recited in the claims. Regarding the specification, page 9, lines 13-21, said passage refers to oligonucleotides used as probes to detect the DNA encoding TBP-II. This is not the claimed invention. The specification page 16 also does not disclose the scope of the claimed invention (e.g. a nucleic acid encoding a fragment with the functional activity recited in the claims). Appellant appears to be arguing that the instant limitation is obvious in view of the disclosure of the specification. However, obviousness is not the appropriate standard with regards to issues of written description.

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The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims. . . ."), the specification must contain an equivalent description of the claimed subject matter. A

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description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

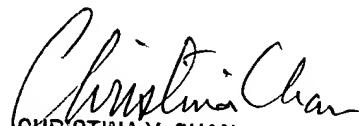
For the above reasons, it is believed that the rejections should be sustained.



Respectfully submitted,

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December 3, 2001



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